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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,365	11/12/2003	Nathan R. Every	00065.01R	1462

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EXAMINER

ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/712,365	Applicant(s) EVERY ET AL.	
	Examiner James H. Alstrum-Acevedo	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-50, 59, 62, 63, 65-69 and 95-106 is/are allowed.
- 6) ☒ Claim(s) 51-58, 60, 61, 64, 70-74, 83-87 and 90-94 is/are rejected.
- 7) ☒ Claim(s) 58, 75, 76, 88 and 89 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 32-106 are pending. Applicants' have cancelled claims 1-31. Receipt and consideration of Applicants' claim amendments and remarks/arguments, submitted on May 17, 2006 is acknowledged.

Specification

The objection to the abstract as set forth in the record on page 2 of the previous office action **is withdrawn**, per Applicants' amendments.

The objection to the specification for the improper use of the trademark TEFLON® (on pages 24-27) **is withdrawn**, per Applicants' amendments.

Claim 58 is objected to because of the following informalities: there are two claims numbered "58" in the instant set of pending claims. There is currently no claim 59. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 82 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 82 is indefinite because there is no specific drug recited after the amount of drug condensation aerosol that is to be administered in a method of treatment. A person

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of ordinary skill in the art would be unable to divine which specific drug from the list claimed in independent claim 70 Applicant intended.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-31 under 35 U.S.C. 103(a) as being unpatentable over Venkataraman (US 2001/0039262 A1) in view of Bartus et al. (U.S. Patent No. 6,514,482) in further view of Byron (US 2004/0016427) is moot, because said claims have been cancelled. Applicants' remarks/arguments regarding this rejection as it may apply to new claims 32-69 and 95-106 have been found persuasive.

Claims 70-74 and 83-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkataraman (US 2001/0039262 A1) in view of Bartus et al. (U.S. Patent No. 6,514,482) in further view of Byron (US 2004/0016427) for the reasons of record.

It is noted that in claims 70-74 and 83-87 Applicant is claiming a method of treatment comprising administering a therapeutic amount of known drugs to treat known conditions treated by administration of diuretics (i.e. a class of pharmaceutical compounds to which the drugs listed in claims 70 and 83 belong).

Claims 77-82 and 90-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkataraman (US 2001/0039262 A1) in view of Bartus et al. (U.S. Patent No. 6,514,482) in further view of Byron (US 2004/0016427) as applied to claims 70-74 and 83-87 above, and further in view of Puschett, J. B. "Diuretics and

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the Therapy of Hypertension,” *J. Med. Sci.*, January 2001, *Vol. 319(1)*, pp 1-9 or Lant, A. “Diuretic Drugs. Progress in Clinical Pharmacology,” *Drugs*, 1986, 31 Suppl. 4, pp 40-55 (abstract) or Gottlieb, S. S. “Renal Effects of Adenosine A1-Receptor Antagonists in Congestive Heart Failure,” *Drugs*, 2001, 61(10), pp 1387-1393 (abstract).

Applicant Claims

Applicant claims (1) a method of treating edema comprising administration of a drug condensation aerosol of a drug selected from the group consisting of bumetanide, ethacrynic acid, furosemide, muzolimine, spironolactone, torsemide, triamterene, tripamide, BG 9928, and BG 9719 and (2) a method of treating congestive heart failure comprising administration of one of the drugs listed in (1).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Venkataraman, Bartus, and Byron have been set forth in the record on pages 3-10 of the previous office action. Puschett reviews the use of diuretics and the therapy of hypertension utilizing diuretics. In Table 4, Puschett teaches suggested therapeutic dosages of several diuretics including, **furosemide, bumetanide, ethacrynic acid, torsemide, spironolactone, and triamterene** (spelled as triamterine in Table 4). Lant teaches a review of the literature concerning diuretic drugs in the context of clinical pharmacology (abstract). Muzolimine is identified as a diuretic. Gottlieb teaches that adenosine A1-receptor antagonists have been suggested to cause a diuretic effect and that these compounds decrease afferent arteriolar pressure (abstract).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Venkataraman, Bartus, and Byron lack the teaching that muzolimine, torsemide, tripamide, and triamterene are diuretics as well as suggested therapeutic amounts of bumetanide, ethacrynic acid, furosemide, spironolactone, torsemide, triamterene, and tripamide. These deficiencies are cured by the teachings of Puschett or Lant and/or Gottlieb, which have been provided to demonstrate that the drugs listed in claims 70 and 83 are known diuretics utilized for the treatment of congestive heart failure and edema in the dosage amounts claimed by Applicant.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Venkataraman, Byron, and Bartus with the teachings of Puschett and Lant, because Puschett and Lant review the medical literature with regards to the use of diuretic drugs in the treatment of congestive heart failure and edema. A skilled artisan would have been motivated to turn to these literature review articles for guidance with regards to suggested dosage amounts and information regarding these drugs useful in a clinical setting to treat patients suffering from edema and congestive heart failure. A skilled artisan would have had a reasonable expectation of success upon combination of the prior art references, because diuretics are a well-known class of drugs that are art recognized for the treatment of edema and congestive heart failure.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejections set forth on the record on pages 11-18 under the judicially created doctrine of obviousness-type double patenting **are moot**, because Applicants have cancelled the rejected claims. **The following claims are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over the cited copending applications: (1) claim 51 as being unpatentable over claim 12 of copending Application No. 10/057,197 (copending '197); (2) claims 51 and 60 as being unpatentable over claim 28 of copending Application No. 10/146,086 (copending '086); (3) claims 51 and 60 as being unpatentable over claims 12 and 18 of copending Application No. 10/633,876 (copending '876); and (4) claims 51 and 60 as being unpatentable over claims 15 and 21 of copending Application No. 10/633,877 (copending '877) are made for the reasons set forth on the record.**

Previously, provisional rejections were made under the judicially created doctrine of obviousness-type double patenting over copending applications 10/718,982 and

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10/768,205. These copending applications have now issued as U.S. patents and the originally rejected claims have been cancelled. **New rejections under the judicially created doctrine of obviousness-type double patenting follow: (1) claim 51, 60-61, and 64 as being unpatentable over claims 1, 2, 4, 74, 79, and 82 of copending Application No. 10/718,982 in view of Venkataraman (copending '982 has issued, but has not yet been assigned a U.S. Patent number); and (2) claims 32, 40, and 51-52 as being unpatentable over claims 1, 7-9, and 18-19 of copending Application No. 10/768,205 (copending '205 has since issued as U.S. Patent No. 7,070,765) are now non-provisional rejections, because said copending applications have issued.**

Claims 51 and 54-58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 10, and 18 of U.S. Patent No. 6,737,046 (U.S. Patent No. '046). Although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps of the instant application and USPN '046 are substantially overlapping in scope. Independent claim 9 of USPN '064 teaches the steps of (a) volatilizing a drug ester under conditions sufficient to produce a heated vapor of said ester and (b) passing air through the heated vapor to produce aerosol particles of the drug vapor comprising less than 5% drug ester degradation products and having an MMAD of less than 3 microns. Steps (a) and (b) of USPN '046 claim 9 read on steps (a) and (b) of independent claim 51 of the instant application, respectively, which require the formation of a drug aerosol by heating and characterized by having less than 10% degradation products and a MMAD of less than 5 microns.

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Claims 51-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-12 of copending Application No. 11/370,628 (copending '628). Although the conflicting claims are not identical, they are not patentably distinct from each other because the steps of the methods claimed in the cited claims of the instant application and copending application are overlapping in scope. Both claim sets claim methods of generating aerosols comprising the steps of (a) heating a thin film (i.e. coating) of a drug on a solid support to volatilize said drug and (b) passing a stream of air through said vapor to form aerosol particles of said drug (condensation aerosols are aerosol particles), wherein the aerosol particles are characterized by less than 10% degradation products of said drug and a MMAD of less than 5 microns. The difference between the cited claims of both applications is the drug coated onto the solid support is not the same. Albeit this difference, the steps claimed in said methods are fundamentally the same. It would have been obvious to a person of ordinary skill in the art that one could volatilize other drugs utilizing this same method, as evidenced by the cited claims of the instant application and copending '628.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The list below of U.S. Patents and copending U.S. patent applications have been found to claim substantially similar subject matter per the obviousness-type double patenting rejections made above in the instant office action as well as those set forth in

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the record on pages 11-18 of the previous office action. It is incumbent upon Applicant to review this list and file terminal disclaimers as appropriate.

U.S. Patent/Application Number	U.S. Patent/Application Number	U.S. Patent/Application Number	U.S. Patent/Application Number
1. 6,805,853 (Patent)	19. 6,737,043 (Patent)	37. 7,011,819 (Patent)	55. 10/766,149 (Patent)*
2. 6,797,259 (Patent)	20. 6,759,029 (Patent)	38. 7,014,840 (Patent)	56. 10/766,279 (Patent)*
3. 6,780,399 (Patent)	21. 6,803,031 (Patent)	39. 7,022,312 (Patent)	57. 10/766,566 (Patent)*
4. 6,780,400 (Patent)	22. 6,805,854 (Patent)	40. 7,014,841 (Patent)	58. 10/766,634 (Patent)*
5. 6,716,415 (Patent)	23. 7,029,658 (Patent)	41. 6,994,843 (Patent)	59. 10/766,647 (Patent)*
6. 6,855,310 (Patent)	24. 7,008,615 (Patent)	42. 7,008,616 (Patent)	60. 10/768,205 (Patent)*
7. 6,783,753 (Patent)	25. 7,018,619 (Patent)	43. 7,052,680 (Patent)	61. 10/768,220 (Patent)*
8. 6,716,416 (Patent)	26. 7,005,121 (Patent)	44. 7,078,016 (Patent)	62. 10/768,281 (Patent)*
9. 6,743,415 (Patent)	27. 7,045,118 (Patent)	45. 10/437,643 (Appl.)	63. 10/768,293 (Patent)*
10. 6,740,307 (Patent)	28. 7,052,679 (Patent)	46. 10/719,899 (Appl.)	64. 10/769,046 (Patent)*
11. 6,740,307 (Patent)	29. 7,033,575 (Patent)	47. 10/735,199 (Patent)*	65. 10/769,157 (Patent)*
12. 6,814,954 (Patent)	30. 7,018,620 (Patent)	48. 10/735,497 (Patent)*	66. 10/768,197 (Patent)*
13. 6,884,408 (Patent)	31. 7,048,909 (Patent)	49. 10/749,535 (Patent)*	67. 10/792,013 (Patent)*
14. 6,740,308 (Patent)	32. 7,005,122 (Patent)	50. 10/749,536 (Patent)*	68. 10/813,272 (Patent)*
15. 6,776,978 (Patent)	33. 7,048,909 (Patent)	51. 10/749,537 (Patent)*	69. 10/814,998 (Appl.)
16. 6,740,309 (Patent)	34. 7,005,122 (Patent)	52. 10/749,539 (Patent)*	70. 11/248,598 (Appl.)
17. 6,814,955 (Patent)	35. 7,045,119 (Patent)	53. 10/749,783 (Patent)*	71. 11/370,628 (Appl.)

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18. 6,716,417 (Patent)	36. 7,018,621 (Patent)	54. 10/750,303 (Patent)*	72. 11/398,383 (Appl.)
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* These applications have issued, but have not yet been assigned a patent number.

Claim Objections

Claims 75, 76, 88, and 89 are objected for depending upon a rejected claim.

Response to Arguments

Applicant's arguments, see pages 2-6, filed May 17, 2006, with respect to claims 1-31 (now cancelled) and as applied to new claims 32-106 have been fully considered and are persuasive. The rejection of claims 1-31 is moot, because said claims have been cancelled and this rejection has been withdrawn as it may have applied to new claims 32-106. It is noted that Applicant has not traversed the obviousness-type double patenting rejections set forth in the record on pages 11-18 of the previous office action and has stated their intention to file terminal disclaimers, once the instant application is in condition for allowance.

Applicant's arguments with respect to claims 32-106 have been considered but are moot in view of the new ground(s) of rejection (see new double patenting rejections).

Conclusion

Claim 58, 75, 76, 88, and 89 are objected. Claims 51-58, 60-61, 64, 70-74, 83-87, and 90-94 are rejected. Claims 32-50, 59, 62, 63, 65-69 and 95-106 are allowed.

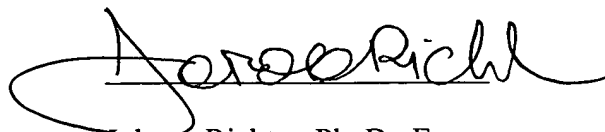
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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